

REMARKS

Claims 26-29, 32-35, and 40-49 were pending in the application. By this amendment, claims 26, 45, and 48 have been amended. Accordingly, claims 26-29, 32-35, and 40-49 remain pending.

The following remarks are in response to the rejections of claims and other matters set forth in the Office Action.

Claims Rejected Under 35 U.S.C. § 103

Claims 26-29, 32-35, and 40-49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Suzuki et al. (US 2002/0111534) in view of Jaffe (US 2002/0161281). Without acceding to any of the Examiner's stated grounds for rejecting the claims, Applicants respond as follows.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Each of the independent claims – claims 26, 45, and 48 – recites an apparatus for performing a medical procedure having, *inter alia*, an overtube, a first catheter, and a flexible delivery catheter having a needle and being adapted to deliver an anchor assembly and secure a tissue fold. In the previous amendment, each of these claims was amended to further recite a flexible push rod that is adapted to deploy the anchor assembly from a distal end of the flexible delivery catheter. By this amendment, each of

these claims has been further amended to clarify the relationship between the flexible push rod and the needle, i.e., by reciting:

the ~~anchor delivery system~~ flexible delivery catheter further comprising a flexible push rod that is slidably disposed within [[the]] an internal lumen of the ~~flexible delivery catheter~~ needle and that is adapted to deploy the anchor assembly from [[a]] the distal [[end]] portion of the ~~flexible delivery catheter~~ needle.

Support for these features is provided throughout the specification such as, for example, at paragraphs 0087-90 and at FIGS. 4A-C. As explained in Applicants' prior response, this feature, in combination with the other features recited in claims 26, 45, and 48, provide the recited apparatus with the ability to expel an anchor assembly out of the distal end of the flexible delivery catheter, as described in the specification. This is a patentable distinction between the claimed apparatus and the devices described in the Suzuki publication and the other cited art, which do not teach an apparatus having the recited combination that includes the flexible push rod disposed within an internal lumen of the needle.

More particularly, the Suzuki publication describes an apparatus that includes a sheath 84, a first endoscope 2 and a second endoscope 6 insertable through the sheath 84, and a suture retaining device 50 that is insertable through a guide 5 running lengthwise on the outer periphery of the first endoscope 2. (See Suzuki, Fig. 1, paragraphs 0038-39). The second endoscope 6 includes a needle tool 40 that has a needle 44 and a suture 46 inserted slidably in the lumen of the needle 44. (Suzuki, Figs. 7-9, paragraph 0044). Upon deployment, the suture 46 is grasped by the suture retaining device 50 and pulled through the needle 46. (Suzuki, Figs. 17-19, paragraph 0058). Upon deployment of a second suture 46b, a knot pusher 50 is used to advance a knot 105 to tie the sutures. (Suzuki, Figs. 22-25, paragraph 0061). The knot pusher 50 is not described as being disposed within the needle 44, or of even being capable of being disposed within the needle 44. As a result, the Suzuki apparatus does not include the recited "flexible push rod that is slidably disposed within an internal lumen of the needle."

The Jaffe publication does not provide any teaching or suggestion that corrects these deficiencies. The Jaffe device does not include an anchor delivery system. Nor is

there any teaching or suggestion in either of the Suzuki or Jaffe publications (or the art in general) that either of the devices should be modified to include a flexible push rod disposed within an internal lumen of a needle, as recited in claims 26, 45, and 48.

Accordingly, because at least these limitations recited in claims 26, 45, and 48 are not taught or suggested by the Suzuki or Jaffe publications, the Office Action fails to establish a *prima facie* case of obviousness of claims 26, 45, and 48 or the claims dependent therefrom. Applicants respectfully request withdrawal of the rejections of claims 26-29, 32-35, and 40-49.

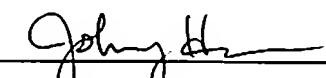
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented, but rather as an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02513**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,


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